FDA 510(k) Premarket Notification

CLEARED

K221613 Freestyle Lancing Device II, Autolet, Autolet Lite, Unilet Lancets

Oct 3, 2022
122 days to decision

K221613 · Product code: **QRL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k221613/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Use Blood Lancet For Single Patient Use Only (QRL)
Date received	Jun 3, 2022
Decision date	Oct 3, 2022
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Owen Mumford, Ltd.**
Location	Marietta, GA, US
Contact	Darren Mansell
Website	http://www.owenmumford.com/us/
510(k) history	13 submissions · 13 cleared · 2000-2023

Owen Mumford, Ltd. is a global medical device manufacturer with over 70 years of experience designing and manufacturing innovative healthcare solutions. The company specializes in drug delivery systems, blood collection devices, and safety lancets for both clinical and home use. Owen Mumford operates with a manufacturing facility in Marietta, US, and serves healthcare professionals and patients worldwide. The company has received FDA 510(k) clearances from total submissions, spanning from 2000 to 2023. Owen Mumford's cleared devices focus primarily on General Hospital app...

REGULATORY CONSULTANT

Consulting firm	**Owen Mumford USA, Inc.**
Contact	Patty Cronan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov